I. Amendment

Claim 1 (original): An oral composition for use in treating benign prostatic hyperplasia, comprising:

a saw palmetto extract; and

a controlled release system, said system comprising:

a coating formed from a material impervious to acidic conditions in the stomach that is soluble in the duodenum and small intestine.

Claim 2 (original): The composition of claim 1, wherein the controlled release system prevents the saw palmetto extract from being degraded in the stomach.

Claim 3 (currently amended): The composition of claim 1, wherein the controlled release system comprises a system selected from the group consisting of microencapsulation in coatings of variable thickness, each with a different dissolution pattern; ~~and~~ capsulation in a material matrix that dissolves slowly in the neutral environment of the duodenum and small intestine; and binding bioadhesives that adhere to the wall of the small intestine.

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Claim 4 (original): The composition of claim 1, wherein the composition further comprises a compound that minimizes smooth muscle contractions.

Claim 5 (original): The composition of claim 4, wherein the compound that minimizes smooth muscle contractions is an antispasmodic compound selected from the group consisting of Belladonna Alkaloid, Choleus Forskholi, European Goldenrod, Peppermint, and Passion Fruit seed.

Claim 6 (original): An oral composition for improving the effectiveness of saw palmetto extract therapy, comprising:

a saw palmetto extract; and

a controlled release system, said system comprising:

a coating formed from a material impervious to acidic conditions in the stomach that is soluble in the duodenum and small intestine.

Claim 7 (original): The composition of claim 6, wherein the controlled release system prevents the saw palmetto extract from being degraded in the stomach.

Claim 8 (currently amended): The composition of claim 6, wherein the controlled release system comprises a system selected from the group consisting of microencapsulation in coatings of variable thickness, each with a different dissolution pattern; ~~and~~ capsulation in a material matrix that dissolves slowly in the neutral environment of the duodenum and small intestine; and binding bioadhesives that adhere to the wall of the small intestine.

Claim 9 (original): The composition of claim 6, wherein the composition further comprises a compound that minimizes smooth muscle contractions.

Claim 10 (original): The composition of claim 9, wherein the compound that minimizes smooth muscle contractions is an antispasmodic compound selected from the group consisting of Belladonna Alkaloid, Choleus Forskholi, European Goldenrod, Peppermint, and Passion Fruit seed.

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Claim 11 (currently amended): An <u>improved</u> oral saw palmetto extract composition, the improvement comprising:

a compound that reduces smooth muscle contractions; and

a controlled release system, said system comprising:

a system selected from the group consisting of microencapsulation in coatings of variable thickness, each with a different dissolution pattern; encapsulation in a material matrix that dissolves slowly in the neutral environment of the duodenum and small intestine; and binding with bioadhesives that adhere to the wall of the small intestine.

Claim 12 (original): A method of treating benign prostatic hyperplasia, comprising the step of:

administering a therapeutically effective amount of a saw palmetto extract which comprises an oral delivery vehicle comprising a coating formed from a material impervious to acidic conditions in the stomach that is soluble in the duodenum and small intestine.

Claim 13 (original): The method of claim 12, wherein the saw palmetto extract is released

into the bloodstream over an extended period.

Claim 14 (currently amended): The composition of claim 6, wherein the controlled release system comprises a system selected from the group consisting of microencapsulation in coatings of variable thickness, each with a different dissolution pattern; ~~and~~ capsulation in a material matrix that dissolves slowly in the neutral environment of the duodenum and small intestine; and binding bioadhesives that adhere to the wall of the small intestine.

Claim 15 (original): The method of claim 12, wherein the coating passes through the stomach intact.

Claim 16 (original): The method of claim 12, wherein the saw palmetto extract is initially released in the duodenum.

Claim 17 (original): The method of claim 12, wherein the saw palmetto extract is released before it enters the colon.

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Claim 18 (original): A method of improving the efficacy of saw palmetto extract treatment, comprising the steps of:

providing a therapeutically effective amount of a saw palmetto extract in an oral formulation; and

encapsulating the saw palmetto extract in a coating formed from a material impervious to acidic conditions in the stomach that is soluble in the duodenum and small intestine.

Claim 19 (original): The method of claim 18, wherein the saw palmetto extract is released into the bloodstream over an extended period.

Claim 20 (currently amended): The composition of claim 6, wherein the controlled release system comprises a system selected from the group consisting of microencapsulation in coatings of variable thickness, each with a different dissolution pattern; ~~and~~ capsulation in a material matrix that dissolves slowly in the neutral environment of the duodenum and small intestine; and binding bioadhesives that adhere to the wall of the small intestine.

Claim 21 (original): The method of claim 18, wherein the coating passes through the stomach intact.

Claim 22 (original): The method of claim 18, wherein the saw palmetto extract is initially released in the duodenum.

Claim 23 (original): The method of claim 18, wherein the saw palmetto extract is released before it enters the colon.

Claims 24-27 (cancelled).